

WHAT IS CLAIMED IS:

1 1. A sample collection device for collecting a biological sample from
2 a mammary organ of a patient, comprising:

3 a breast engaging member constructed of a non-porous material
4 sized and dimensioned to receive at least a nipple portion of a breast of said patient and
5 form a suction seal therewith;

6 a solid phase sample collection medium in fluid connection with
7 said breast engaging member for receiving a sample of expressed breast fluid; and

8 vacuum pump means in gaseous connection with said breast
9 engaging member for generating negative pressure through the breast engaging member
10 to facilitate breast fluid expression, wherein the sample collection device is a hand-held
11 breast pump incorporating said breast engaging member and vacuum pump means in a
12 compact, structurally integrated breast fluid collection apparatus that can be manipulated
13 and operated with one hand.

1 2. The sample collection device of claim 1, wherein said solid phase
2 sample collection medium is selected from the group consisting of microscopic glass
3 slides, capillary tubes, collection tubes, columns, micro-columns, wells, plates,
4 membranes, filters, resins, inorganic matrices, beads, resins, particulate chromatographic
5 media, plastic microparticles, latex particles, coated tubes, coated templates, coated
6 beads, coated matrices, or a combination thereof.

1 3. The sample collection device of claim 1, wherein said hand-held
2 breast pump comprises a modular device formed of a plurality of components that are
3 joined or securable in fixed structural interconnection with one another and may be
4 partially or completely disassembled to remove or uncouple the individual components as
5 desired for efficient operation, cleaning, servicing and/or storage.

1 4. The sample collection device of claim 3, wherein said modular
2 breast pump device includes a separate breast engaging member constructed of a rigid or
3 semi-rigid, non-porous material sized and dimensioned to receive at least a nipple or
4 areolar portion of a human subject's breast and form a suction seal therewith, wherein

5 said breast engaging member is detachable from one or more interconnecting components
6 of the hand-held pump device for cleaning and sterilization or to allow for interchanging
7 of different engaging members to accommodate breast anatomy differences among
8 patients.

1 5. The sample collection device of claim 1, wherein said solid phase
2 sample collection medium is supported by a support member removably mounted in fluid
3 connection with said breast engaging member.

1 6. The sample collection device of claim 5, wherein said support
2 member is provided as a removable cassette that can be inserted within said breast
3 engaging member to be removably mounted in fluid connection therewith.

1 7. The sample collection device of claim 5, wherein said support
2 member supports one or more pads or sheets of absorbent or adsorbent material.

1 8. The sample collection device of claim 1, wherein said solid phase
2 sample collection medium comprises a nitrocellulose membrane.

1 9. The sample collection device of claim 8, wherein said
2 nitrocellulose membrane has a pore size selected to effectively retain whole cells from
3 expressed breast fluid on a surface of the membrane.

1 10. The sample collection device of claim 7, wherein the pad or sheet
2 is a modified membrane or filter having perforations or slits that disrupt the planar surface
3 of the membrane or filter to facilitate air passage therethrough and impart structural
4 flexibility against mechanical perturbation.

1 11. The sample collection device of claim 5, wherein said support
2 member incorporates one or more air channels that pass through a body of the support
3 member for passage of vacuum pressure therethrough and/or to serve as channels for
4 passage of breast fluid sample materials between the breast engaging member and a
5 sample collection housing member of the hand-held breast pump.

1 12. The sample collection device of claim 1, further comprising a
2 fluid-retaining recess, well or reservoir integrated or fluidly connected with the support
3 member or a sample collection housing member of the hand-held pump device.

1 13. The sample collection device of claim 12, wherein the fluid-
2 retaining recess, well or reservoir comprises an integral, defined compartment or
3 enclosure within the sample collection housing for receipt of breast fluid and/or
4 constituent samples thereof

1 14. The sample collection device of claim 12, wherein the fluid-
2 retaining recess, well or reservoir comprises a removable fluid reservoir member of the
3 sample collection housing.

1 15. The sample collection device of claim 14, wherein the removable
2 reservoir member is a rigid sample collection tube or vial removably connected with an
3 outer casing member of the housing that partially or completely encloses the tube or vial.

1 16. The sample collection device of claim 14, wherein the removable
2 reservoir member is a rigid sample collection tube or vial removably, sealably connected
3 with an outer casing member of the housing to form an airtight coupling therewith.

1 17. The sample collection device of claim 14, wherein the removable
2 reservoir member is a cytology vial sealably connected with an outer casing member of
3 the housing to form an airtight coupling therewith.

1 *sub a 7* 18. The sample collection device of claim 17, wherein the removable
2 reservoir member and outer casing member of the housing are coupled to form an
3 assembled sample collection housing, wherein the reservoir member is removably nested
4 within the casing member to form a substantially airtight contact between an inner wall of
5 the casing member wall and an outer wall, or a top or bottom end, of the reservoir
6 member.

1 19. The sample collection device of claim 18, wherein an outer wall of
2 the removable reservoir member features a circumferential ridge, fin or O-ring that

3 engages and makes a circumferential airtight seal against the inner wall of the casing
4 member when the vial is nested within the casing member.

1 20. The sample collection device of claim 14, wherein the removable
2 reservoir member is gaseously and fluidly connected with the breast engaging member to
3 facilitate sample collection.

1 21. The sample collection device of claim 14, wherein vacuum
2 pressure from the vacuum pump means is routed to the breast engaging member through
3 the removable reservoir member of the housing.

1 22. The sample collection device of claim 21, wherein the removable
2 reservoir member is modified to include one or more air ports that form a gaseous
3 connection between a lumen of the reservoir and the vacuum pump means.

1 *sub 87* 23. The sample collection device of claim 14, wherein the removable
2 reservoir member functions as both a conduit for vacuum pressure transmission to the
3 breast and a receptacle for fluid sample materials to directly collect expressed fluid or as a
4 secondary collection medium to receive primarily collected sample materials washed or
5 otherwise transferred from a primary solid phase sample collection medium.

1 24. The sample collection device of claim 14, wherein the removable
2 reservoir member communicates for fluid and gaseous transmission directly with the
3 breast engaging member or indirectly therewith by way of air channels in a support
4 member optionally coupled with the breast engaging member.

1 *sub a9* 25. The sample collection device of claim 14, wherein a primary solid
2 phase sample collection medium fluidly connected with the breast engaging member is
3 positioned to collect a primary sample of one or more breast fluid components which can
4 thereafter be washed or otherwise transferred directly or indirectly into the removable
5 reservoir member without removal or disassembly of the breast engaging member and
6 reservoir member.

1 26. The sample collection device of claim 25, wherein the primary
2 solid phase sample collection medium is a nitrocellulose membrane for retaining cells and
3 other cytological materials on a surface of the membrane.

1 27. The sample collection device of claim 25, wherein the primary
2 sample collection medium is supported in fluid connection with the breast engaging
3 member by a support member, and wherein the support member includes one or more
4 sample transfer channels for transfer of the primary sample from the primary collection
5 medium, through the channels into the removable reservoir.

1 *sub all* 28. The sample collection device of claim 27, wherein the sample
2 transfer channels extend through tubular basal columns or other fluid connection ports
3 that extend from the support member toward, or into, a lumen of the fluid reservoir
4 member.

1 29. The sample collection device of claim 14, wherein the removable
2 reservoir member is a cytology vial having one or more air ports that communicate
3 between an outer wall and inner lumen of the vial to form a gaseous connection between
4 the lumen of the vial, the vacuum pump means, and the breast engaging member.

1 *sub all* 30. The sample collection device of claim 14, wherein the removable
2 reservoir member further comprises closure means for closure of the reservoir after
3 sample collection is completed to prevent sample contamination and spillage, whereby
4 the removable reservoir serves a multi-purpose function for sample collection as a
5 component of the breast pump device as well as for storage, transport and/or processing
6 of the sample upon removal of the reservoir member from the device.

1 31. The sample collection device of claim 30, wherein the closure
2 means comprises a cap adapted to sealably engage a top end of the removable reservoir
3 member.

1 *sub all* 32. The sample collection device of claim 30, wherein the reservoir
2 member is modified to include one or more air ports that form a gaseous connection
3 between a lumen of the reservoir and the vacuum pump means when the reservoir
4 member is engaged with the pump device, and wherein the closure means further
5 comprises secondary closure means to sealably close the air port(s) after sample
6 collection.

1 33. The sample collection device of claim 32, wherein said secondary
2 closure means comprise an adhesive seal or sticker sized and constructed to adhere to an
3 outer wall of the reservoir member surrounding an air port opening.

1 34. The sample collection device of claim 32, wherein said secondary
2 closure means comprises a combined closure and labeling device which functions as a
3 secondary closure mechanism to seal the air port(s) of the removable reservoir and as a
4 labeling template to provide a writing surface for sample labeling.

1 35. The sample collection device of claim 32, wherein said secondary
2 closure means comprises a combined closure and labeling tab or sticker which may be
3 directly applied to seal the air port after sample collection having a first, closure-forming
4 surface for application over the air port to form a seal by juxtaposition or adhesive contact
5 with an outer wall of the removable reservoir, and a second, labeling surface opposite the
6 closure-forming surface made of a blank template material suitable for receiving a stable,
7 ink or graphite imprint thereon.

1 36. The sample collection device of claim 35, wherein said first,
2 closure-forming surface bears an adhesive coating resistant to disruption by contact with
3 aqueous solutions.

1 37. The sample collection device of claim 32, wherein said secondary
2 closure means comprises a combined closure and labeling tab or sticker which is pre-
3 attached to the removable reservoir member in a first, open configuration and can be
4 manually repositioned or otherwise manipulated after sample collection to a second,
5 closed configuration to form a seal or closure against the air port(s).

1 38. The sample collection device of claim 37, wherein said secondary
2 closure means comprises an adhesive tab or strip folded in the open configuration to form
3 an inner layer affixed to the reservoir proximate to the air port and an outer layer folded
4 over the inner layer, said outer layer providing the first, closure-forming surface and the
5 second, labeling surface, wherein the outer layer can be unfolded away from the inner
6 layer and wrapped around the reservoir so that the closure-forming surface covers the air
7 port to form a fluid-resistant closure and the labeling surface faces outward for
8 recording of sample data.

1 39. The sample collection device of claim 38, wherein the outer layer
2 is optionally secured in a folded-back position against the inner layer by adhesive
3 engagement of the labeling surface with the inner layer.

1 40. The sample collection device of claim 39, wherein said first,
2 closure-forming surface bears an adhesive coating that is protected in the open
3 configuration by folding of an end segment of the outer layer bearing the adhesive coating
4 back, so that the closure forming surface provides a protective surface to shield the
5 adhesive prior to closure, whereby the end segment can be lifted and pulled outward to
6 unfold the end segment to separate the adhesive coating on the closure-forming surface
7 from the protective surface and to release the outer layer from the inner layer for closing
8 of the air port(s).

1 41. The sample collection device of claim 14, wherein the breast
2 engaging member includes removable coupling means for removable coupling of the
3 breast engaging member with a complementary coupling surface of the sample collection
4 housing.

1 42. The sample collection device of claim 41, wherein the sample
2 collection housing includes an outer casing member and a removable, fluid reservoir
3 member, and wherein the engaging member can be directly coupled to the fluid reservoir
4 member.

1 43. The sample collection device of claim 42, wherein the breast
2 engaging member has coupling threads to engage complementary threads of an open end
3 of the removable reservoir, said complementary threads of the reservoir adapted to
4 interchangeably receive a cap that sealably engages the reservoir open end.

1 44. The sample collection device of claim 43, wherein the removable
2 reservoir member is a modified cytology vial.

1 45. The sample collection device of claim 1, wherein the solid phase
2 sample collection medium is adjustably mounted relative to the sample collection housing
3 so that the solid phase collection medium can be controllably moved closer to, or farther
4 away from, a base of the engaging member of the pump during use.

1 46. The sample collection device of claim 1, further comprising a
2 reciprocating mechanism which adjustably moves the solid phase sample collection
3 medium in closer, or more distant, proximity to the nipple when the hand-held breast
4 pump is engaged therewith.

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1 47. The sample collection device of claim 1, further comprising a
2 compact vacuum pump housing which structurally and functionally integrates the vacuum
3 pump with the sample collection housing.

1 48. The sample collection device of claim 47, wherein the vacuum
2 pump housing and outer casing member of the sample collection housing are cast or
3 molded as a single, integral component of the device.

1 49. The sample collection device of claim 1, further comprising a
2 vacuum pump actuating mechanism connected to a vacuum pump housing of the device.

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1 50. The sample collection device of claim 49, wherein the vacuum
2 pump actuating mechanism comprises an actuating lever pivotally connected to the pump
3 housing.

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1 51. The sample collection device of claim 49, wherein the pump
2 housing includes an integral handle opposing an actuating lever pivotally connected to a
3 base portion of the handle.

1 52. The sample collection device of claim 1, wherein the vacuum
2 pump means comprises a flexible diaphragm member and pump actuation means to draw
3 the diaphragm member away from a primary vacuum chamber connected with, or
4 integrated within, the sample collection housing.

1 53. The sample collection device of claim 52, further comprising a
2 vacuum pump housing, wherein the primary vacuum chamber is integrally formed within
3 the vacuum pump housing proximate the flexible diaphragm member and extends to a
4 communicating port opening to the sample collection housing.

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2 54. The sample collection device of claim 53, further comprising a
3 removable fluid reservoir member of the housing modified to include one or more air ports
4 that form a gaseous connection between a lumen of the reservoir and the communication port
to gaseously connect the lumen of the reservoir to the primary vacuum chamber.